UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	MDL NO. 2272
This Document Relates to All Cases	)	Master Docket Case No. 1:11-cv-05468
	)	Honorable Rebecca Pallmeyer

William Colbert, et al. v. Zimmer, Inc., et al.
Eastern District of Pennsylvania, Case No. 2:12-cv-01335-JS

MEMORANDUM IN SUPPORT OF
MOTION FOR SUGGESTION OF REMAND: *COLBERT*

On August 3, 2012, the Judicial Panel For Multidistrict Litigation ordered that this Court is in the best position to determine whether *William Colbert, et al. v. Zimmer, Inc., et al.,* should be included in this multidistrict litigation. Zimmer respectfully submits that it should not. *Colbert* does not involve a *NexGen*® Flex Femoral Component or MIS Total Knee Procedure Stemmed Tibial Component Fixed Bearing Precoat ("5950 MIS Tibial Component") (collectively, the "Subject Products"). Instead, Mr. Colbert's femoral and tibial components are the "standard" *NexGen*® Legacy Posterior Stabilized Option Femoral Component ("*NexGen*® LPS Option") and *NexGen*® A/P Wedged Stemmed Tibial Component ("Wedged Tibia") – neither of which are within the scope of the MDL, and neither of which include the flex design features central to the plaintiffs' theory of defect. As such, *Colbert* should be the subject of a suggestion of remand.

I. ANALYSIS

A. Products Implanted in William Colbert

In October 2006, Mr. Colbert was implanted with at least four knee components: the *NexGen*® LPS Option Femoral Component; *NexGen*® A/P Wedged Stemmed Tibial Component; *NexGen*® Tibial Stem Extension Offset; and, *NexGen*® LPS-Flex Articular Surface.[1] Mr. Colbert's femoral and tibial components did not bear the flex design features to which the plaintiffs point as defects in this MDL.

Mr. Colbert underwent revision surgery in September 2009. To the defendants' knowledge, the only product subsequently replaced in Mr. Colbert's knee is the *NexGen*® LPS-Flex Articular Surface.

B. The Panel Requests This Court's Input On Remand

Zimmer opposed the Conditional Transfer of *Colbert*. Nevertheless, the Panel transferred the matter on August 3, 2012, noting that this Court is in the "best position" to determine whether efficiencies would be achieved by including it in the MDL. Transfer Order, p. 1 (Doc. 781). In doing so, however, the Panel expressed no opinion on the outcome of this Court's analysis.

> Although Zimmer's apparent position is that those actions do not belong in the MDL either, we believe that the transferee judge, the Honorable Rebecca R. Pallmeyer, is in the best position to make such a determination. (citations omitted.) **It may be, for example, that many of the same Zimmer personnel were involved in the development, design, manufacture, regulatory approval process, or marketing of not only the components identified in our centralization order, but also the flex articular surface at issue in Colbert, unless including the action in the MDL will result in sufficient deficiencies. On the other hand, Judge Pallmeyer may conclude that no such overlap exists, or that other reasons counsel against incorporating claims involving such components into the centralization proceedings**.

[1] Mr. Colbert also likely was implanted with a patellar component, but it has not yet been identified.

Transfer Order, pp. 1-2 (emphasis added)(Doc. 781). Should this Court conclude that efficiency is not served by including *Colbert* in the MDL, or if other reasons counsel against incorporating claims involving a standard LPS Femoral Component, Wedged Tibia, and Flex Articulating Surface in the MDL, the Court "should issue a suggestion of remand to the Panel in accordance with Panel Rule 10.1(b)." Transfer Order, p. 2, n.4.

C. *Colbert* Should Be Remanded

This Court should suggest the remand of *Colbert* because its inclusion in the MDL would reduce the MDL's efficiency for a number of reasons.

First, the scope of discovery to date has been governed by the seven products identified in the Panel's August 8, 2011, Transfer Order. *See, e.g.*, CMO-3, Section II(a)(4), p. 2 (Doc. No. 412). Zimmer has produced over *two million* pages of documents, with 26 custodial productions now complete.[2] Should the Court expand this MDL to include cases involving components that are *not* one of the Subject Products, and where no Subject Product has failed, discovery in this MDL would grow exponentially larger and more difficult. The tibial and femoral products implanted in Mr. Colbert – the *NexGen*® LPS Option[3] and *NexGen*® Wedged Tibia – are wholly different from any other components in the MDL, and their design, manufacture, regulatory submissions/approvals, marketing, and sales are different from the Subject Products.

[2] Zimmer anticipates that 34 custodial productions will be completed by August 30, 2012.

[3] The *NexGen*® LPS is a product that was a precursor to, and is distinct from, the *NexGen*® Flex femoral components at issue in the other lawsuits associated with this MDL. The standard *NexGen*® LPS was first designed, developed, and sold by Zimmer in 1995, more than four (4) years before Zimmer released its *NexGen*® Flex femoral components. *See, e.g.*, Master Long Form Complaint And Jury Demand ("Master Complaint"), MDL Case No. 1:11-cv-05468, Doc. No. 211, ¶¶ 53-62. Specifically, in 1995, Zimmer introduced the standard *NexGen*® femoral components (including both the LPS and Cruciate Retaining ("CR") options). (*Id.* at ¶ 9). In 1999, Zimmer introduced the *NexGen*® Flex Femoral Components (in both LPS and CR options), which included design changes that allow them to safely accommodate flexion up to one-hundred fifty-five degrees (155°) for patients that can otherwise achieve it. The MDL plaintiffs to date have alleged only that the *NexGen*® Flex Femoral Components are defective.

Even were discovery limited to the *NexGen*® Flex Articular Surface, that product is completely different than any other included in the MDL to date, as the following diagrams reveal.

Zimmer *NexGen*® LPS-Flex Femoral Component

Zimmer *NexGen*® LPS-Flex Articular Surface

Opening discovery to the Flex Articular Surface, and potentially to the LPS Option and Wedged Tibia, would reduce the efficiency of the MDL and increase the complexity and burden of discovery exponentially.

Second, the inclusion of *Colbert* and matters like it in this MDL would be inefficient because the documents and witnesses at issue are different. The LPS Flex and CR Flex Articular Surfaces each have their own unique regulatory documents, including unique 510K submissions. The Flex Articular Surface development includes distinct design history files, project history files, and a significant number of testing documents associated with the development of the polyethylene material that comprises the articular surface. Furthermore, because of the inherent differences in the material (metal v. poly), design (articulating component v. fixed surface), and use, the material specifications and blueprints for the components are completely different. Zimmer's Flex Femoral Components are manufactured primarily from cobalt-chrome, and the

articular surfaces are made from highly crosslinked polyethylene. As such, the method of manufacture and suppliers of raw materials are different for the Flex Articular Surfaces than the Subject Products.

The inclusion of the Flex Articular Surface in this MDL also likely will add additional custodians to the list of 100 agreed-to custodians for whom custodial files will be collected because certain employees responsible for designing, testing, and manufacturing the Flex Articular Surfaces were not otherwise involved with the Flex Femoral Components or the MIS Tibial Component. Because discovery on the LPS Option, Wedged Tibia, Tibial Stem Extension Offset, and LPS-Flex Articular Surface implanted in Mr. Colbert involve different documents and witnesses than the Subject Products, *Colbert* should be remanded.

Third, no efficiencies will be created by the inclusion of *Colbert* in the MDL, because it does not share the plaintiffs' common defect theories: (1) flex design changes in the Flex Femoral Components somehow causes component loosening; and (2) the 5950 MIS Tibial Component is defective in design. Additional and different discovery, thus, must be undertaken if *Colbert* is included in the MDL regarding whatever theory of defect Mr. Colbert elects to pursue, which will involve different science and scientific issues, different testing, and likely different experts. The scientific literature to be gathered, produced, analyzed, and considered by the Court on *Daubert* and other motions related to whatever theory the plaintiffs advance in *Colbert* necessarily will be distinct from the studies cited by the plaintiffs to date. For example, the *Bollars* study quoted extensively by the plaintiffs in a number of submission and presentations focuses entirely on Flex Femoral Component loosening. P. Bollars, et al., *Femoral component loosening in high-flexion total knee replacement: an in vitro comparison of high-flexion versus conventional designs*, 93-B J. BONE JOINT SURG. [BR], 1679 (2011). The Han and

Cho studies on which the plaintiffs rely heavily also involve only the LPS Flex Femoral Component. Han, *et al.*, *High Incidence Of Loosening Of The Femoral Component in Legacy Posterior Stabilized-Flex Total Knee Replacement*, 89-B J. BONE JOINT SURG. [BR], 1457, 1458-59 (2007) ("… tibial base plates, which were well-fixed"); Cho, *et al.*, *Three- to six-year follow-up results after high-flexion total knee arthroplasty: can we allow passive deep knee bending?*, 19 KNEE SURG SPORTS TRAUMATOL ARTHROSC 899 (2010) (finding possible loosening only of femoral components). In short, because the very heart of the *Colbert* matter – the plaintiffs' theory of defect – will be completely different in *Colbert* than other than MDL cases, it should be the subject of a suggestion of remand.[4]

Fourth, inclusion of *Colbert* inevitably will result inefficiencies given that discovery in this MDL is already well underway. Zimmer already has produced some *two million* pages of documents from 26 custodians. The plaintiffs inevitably will demand that Zimmer go back and re-search, re-scan, and produce more documents from those custodians regarding Mr. Colbert's products, requiring months of work to be re-done, and further causing re-negotiation of the custodial discovery schedule and delaying the schedule for discovery, *Daubert* motions, dispositive motions, and trial settings on which the parties have now agreed. Such inefficiency should not be permitted.

[4] Indeed, inclusion of *Colbert* in the MDL would only confuse the issues because it involves one of the devices to which the plaintiffs point as the gold standard: the *NexGen*® LPS. Since the creation of MDL No. 2272, the plaintiffs have continued to focus on the alleged defectiveness of Zimmer's *NexGen*® Flex Femoral Components, while actually praising the safety and efficacy of the *NexGen*® LPS at issue in *Colbert*. In their recently-filed Master Complaint in the MDL, the plaintiffs state that the standard *NexGen*® LPS at issue in *Colbert* is "very successful with a low revision rate." (Master Complaint, the MDL, 1:11-cv-05468, Doc. No. 211, ¶¶ 57). Also instructive is "Plaintiffs' Technical Memorandum On Knee Anatomy, Total Knee Replacement And The Zimmer NexGen **High-Flexion** Components And MIS Surgical Technique" (the "Technical Memorandum"). The Technical Memorandum states that the standard *NexGen*® femoral components, like the one at issue in *Colbert*, have been "very successful with a low revision rate," and only the "NexGen High-Flex Devices" are at issue in the MDL. *Id.* The plaintiffs do not consider the *NexGen*® LPS to be defective, and it would be wholly inconsistent to include products in the MDL that the plaintiffs do not contend bear a common defect.

For these reasons, Zimmer respectfully submits that *Colbert* should be the subject of a suggestion of remand.

IV. CONCLUSION

From the outset, the plaintiffs sought to consolidate only those lawsuits that involved Zimmer's *NexGen*® Flex Femoral Components and/or the 5950 MIS Tibial Component. Transferring *Colbert* would expand this MDL to include Zimmer's Flex Articular Surfaces, and it would open the door to more than *forty* components bearing the *NexGen*® brand, effectively eviscerating boundaries identified by the Panel's August 8, 2011, Transfer Order. Moreover, the unique discovery to be sought in *Colbert* regarding the materials, research, and development of the polyethylene flex articular surface will have no applicability to the other MDL lawsuits or their common theory of defect. As such, this Court should suggest the remand of *Colbert*.

Respectfully submitted,

Dated: August 10, 2012

FAEGRE BAKER DANIELS LLP

/s/ Andrea Roberts Pierson

Joseph H. Yeager, Jr. (Ind. State Bar #2083-49)
Andrea Roberts Pierson (Ind. State Bar #18435-49-A)
300 North Meridian Street, Suite 2700
Indianapolis, IN 46204
Telephone: (317) 237-0300
Fax: (317) 237-1000
Email: jay.yeager@faegrebd.com
apierson@faegrebd.com

J. Stephen Bennett (Ill. State Bar #6226615)
111 East Wayne Street, Suite 800
Fort Wayne, IN 46802-2600
Telephone: (260) 424-8000
Fax: (260) 460-1700
Email: stephen.bennett@faegrebd.com

Attorneys for Zimmer, Inc., Zimmer Holdings, Inc., Zimmer Surgical, Inc., f/k/a Zimmer Orthopaedic Surgical Products, Inc., Wilson/ Phillips Holdings, Inc., d/b/a Zimmer Wilson/Phillips, Orthopaedic Technologies, LLC, d/b/a Zimmer Tri-State (incorrectly named as (1) Zimmer Tri-State d/b/a Tri-State Orthopaedic, (2) Zimmer Tri-State d/b/a Zimmer, Inc., and/or (3) Zimmer Tri-State d/b/a Tri-State Orthopedic), K. Michael Melia, d/b/a Zimmer Melia & Associates, Inc. (incorrectly named as Zimmer Melia & Associates, Inc.), Zimmer Orthobiologics, Inc., Zimmer US, Inc., and Zimmer Production, Inc.

CERTIFICATE OF SERVICE

I certify that on August 10, 2012, a copy of the foregoing Memorandum In Support Of Motion For Suggestion Of Remand: *Colbert* was filed electronically. Parties may access this filing through the Court's system.

/s/ Andrea Roberts Pierson